

**REMARKS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW IN U.S. PATENT  
APPLICATION NO. 10/618,140 FILED ON 7/10/2003**

Pre-appeal brief review is appropriate in this application because the rejections in the Office Action dated October 15, 2008 contain clear deficiencies. The rejections of claims 1-9 should be withdrawn. As set forth below, the cited reference fails to disclose or suggest the claimed limitations and thus *prima facie* obviousness under 35 U.S.C. § 103(a) has not been established.

Claims 1-9 are pending and stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Vaska, U.S. 2008/0045946 (“Vaska ’946”). These rejections now are traversed.

Independent claim 1 recites a surgical procedure establishing openings through the reflections through which a surgical instrument can pass or penetrate in a sequence along a path to substantially surround the left and right pulmonary veins.

Applicant notes that the presently cited Vaska reference (“Vaska ’946” herein) is in the lineage of the previously cited Vaska patent (“Vaska ’605” herein), and thus is nearly identical in scope to Vaska ’605. During an interview with the Examiner on January 12, 2009, Examiner Lang indicated that Vaska ’946 was newly cited because it included language not present in Vaska ’605 (but having priority basis back to 1999). Specifically, the Examiner pointed to the following language as disclosing a non-preferred embodiment: “The devices and methods will preferably avoid the need for cutting or puncturing the pericardial reflections, however, the pericardial reflections may be cut without departing from the scope of the invention.” Vaska ’946, [0007].

Even assuming *arguendo* that such language is sufficient to establish a non-preferred embodiment of Vaska '946, Applicant maintains that the claimed step and sequence are not met. For ease of explanation, an annotated version of Figure 11 of Vaska '946 is copied below. The annotations are described below.

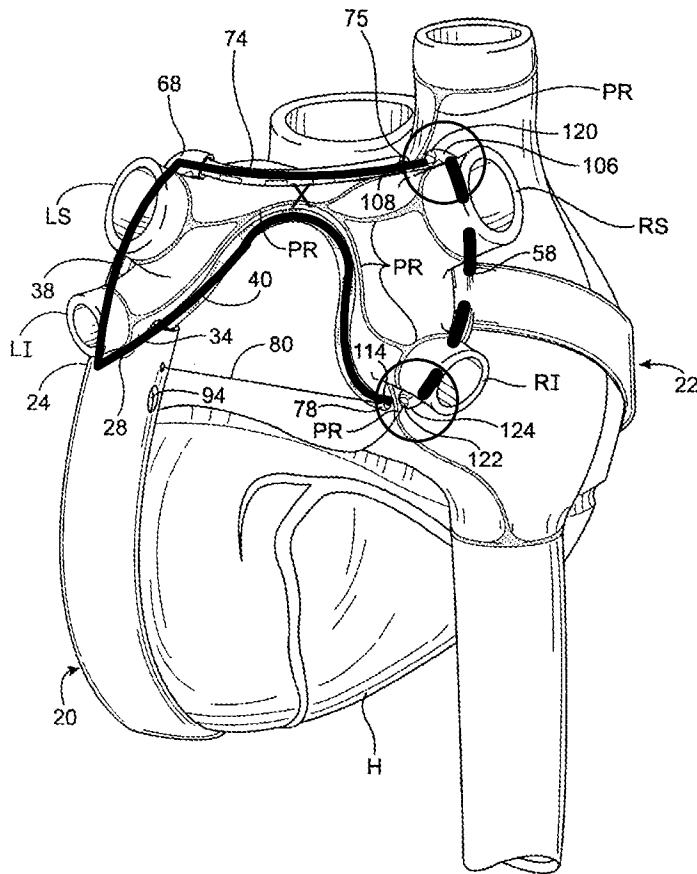


FIG. 10

Vaska '946, as presently understood, merely discloses electrically isolating the pulmonary veins by creating a lesion boundary. *See, e.g.,* Vaska '946, FIG. 11. To create the lesion, left and right ablation probes 20, 22 each extend subprobe arms. The left probe 20 follows the thick, solid black line, extending one arm from below the left inferior pulmonary

vein (LI) around and over the left superior pulmonary vein (LS) and across towards the right superior pulmonary vein (RS), ending at tip 75 at a pericardial reflection. The left probe 20 (solid black line) also extends a second arm from below the LI across towards the right inferior pulmonary vein (RI) conforming upward to the curve of the pericardial reflection, ending at tip 78 at another pericardial reflection. The right probe 22 follows the thick, dashed black line upward to tip 106 and downward to tip 124. Tips 75 and 106 meet on opposite sides of a pericardial reflection, shown circled near the top of the drawing. Tips 78 and 124 meet on opposite sides of another pericardial reflection, shown circled near the middle of the drawing. See Vaska '946, [0089] – [0093], FIGS. 8-11.

Thus, even assuming *arguendo* that the circled pericardial reflections were cut instead of ablated, Vaska '946 still does not disclose the claimed sequence. Specifically, Vaska '946 does not disclose “entering through the opening formed in the first reflection” (between the left and right superior pulmonary veins), and/or “advancing the surgical instrument through the opening formed in the second reflection” (between the superior vena cava and the right superior pulmonary vein), and/or “advancing the surgical instrument through the opening formed in the third reflection” (between the inferior vena cava and the right inferior pulmonary vein). Vaska’s path is very different, as shown in the annotated FIG. 10.

In addition, assuming *arguendo* that Vaska '946 discloses cutting pericardial reflections as a non-preferred embodiment, it would be cutting of only the otherwise ablated reflections, *i.e.*, the ones circled in the above figure. This still would not disclose or suggest “forming an opening in a **first reflection disposed between the left and right superior pulmonary veins**,” as claimed. *I.e.*, the pericardial reflection marked with an X in the figure above.

Applicant further notes that Vaska '946 does not disclose or suggest “advancing the surgical instrument” **through any formed openings** in the reflections to get to the next location. This deficiency is not trivial. First, Vaska '946 does not disclose moving through one reflection to get to another, but rather approaching each of the two reflections separately. Second, additional modifications of Vaska '946 would need to be made to accomplish this change, as the instruments disclosed in Vaska '946 do not include any means for cutting the reflections. Thus, Vaska '946 does not disclose or suggest all steps and sequence of claim 1, and thus the Examiner has failed to establish even a *prima facie* basis from which a proper determination of obviousness under 35 U.S.C. §103(a) can be made.

In addition, the modification of Vaska '946 suggested by the Examiner would take the elements of Vaska '946 well beyond their “established functions,” thus precluding the “predictability” of such a modification. *See KSR*, 550 U.S. 398 (2007). For example, since the instrument of Vaska '946 is for ablating tissue, it is unpredictable how the instrument would be modified such that it would allow for cutting of the pericardial reflections and advancing the instrument through such cuts.

Finding no motivation for such a modification in Vaska '946, the rationale articulated appears to be based on improper hindsight reasoning, impermissibly using knowledge “gleaned only from applicant’s disclosure.” MPEP 2145.

Dependent claims 2-9 depend from claim 1, which was shown above to be patentable over the cited reference. Dependent claims 2-9 also are further limited by such various recitations as “incising the anterior rectus sheath and retracting the rectus muscle to expose the posterior rectus sheath; incising the posterior rectus sheath to expose the inferior border of the costal margin; forming a tract through the incisions and the muscular diaphragm into the pleural

cavity”; or “forming an opening in one of the first, second and third reflections includes grasping a portion of the reflection; and cutting the grasped portion of the reflection to form an aperture therein,” or “grasping through the opening formed in the first reflection the surgical instrument positioned within the transverse pericardial sinus for manipulating therein the surgical instrument through the opening formed in the second reflection,” or “pulling the grasped surgical instrument through the opening formed in the third reflection into the oblique pericardial sinus to substantially complete a loop of the surgical instrument surrounding the left and right pulmonary veins.”

Thus, for at least the above reasons, Vaska '946 fails to establish even a *prima facie* basis from which a proper determination of obvious may be formed for claims 1-9.

Respectfully Submitted,

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By: /Jennifer R. Bush/  
Attorneys for Assignee  
Jennifer R. Bush, Reg. No. 50,784  
FENWICK & WEST LLP  
801 California Street  
Mountain View, CA 94041  
Phone: (650) 335-7213  
Fax: (650) 938-5200